

10023882

JAN 30 2009

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR§807.92(a).

807.92(a)(1)

Submitter Information

Jamie Austin
Anson Group
11460 N. Meridian St., Ste. 150
Carmel, IN 46032
Phone: (317) 569-9500 x 118
Facsimile: (317) 569-9520

Contact Person: Jamie Austin

Date: December 10, 2008

807.92(a)(2)

Trade Name: MyLabFive Ultrasound System

Common Name: Ultrasound Imaging System

Classification Name(s):	Ultrasonic pulse Doppler imaging system	892.1550
	Ultrasonic pulsed echo imaging system	892.1560
	Diagnostic ultrasonic transducer	892.1570

Classification Number: 90IYN, 90IYO, 90ITX

807.92(a)(3)

Predicate Device(s)

K070903	2750 (MyLab40)	Esaote Europe
K081794	7340 (MyLab30 Gold Cardiovascular)	Esaote S.p.A.

Additional substantial equivalence information is provided in the following substantial equivalence comparison table.

807.92 (a)(4)

Device Description

The MyLabFive is a portable ultrasound system used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Multi View (MView), Amplitude Doppler (AD), Tissue Velocity Mapping (TVM) and Tissue Enhancement Imaging (TEI). Optional is Doppler and Color Flow Mapping (CFM). The MyLabFive is equipped with a LCD Color Display. The full alphanumeric keyboard allows complete on-screen data entry of patient information and on-screen annotations. The MyLabFive can drive phased (PA), convex (CA), linear array (LA) and Doppler probes.

The MyLabFive is equipped with an internal Hard Disk and with an optional external DVD-RW disk drive that can be used for image storage. Data can also be stored directly to external archiving media (hard-disk, PC, server) via a LAN/USB port. Optional accessory devices available for the MyLabFive include an S-VHS video recorder; a monochrome or color page printer and a mobile trolley equipped with an insulation transformer.

807.92(a)(5)

Intended Use(s)

Esaote's MyLabFive is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Laparoscopic, Intraoperative Abdominal, and Other Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

Esaote believes that the MyLabFive is substantial equivalent to the Esaote MyLab30 Gold Cardiovascular product (K081794) and Esaote MyLab40 product (K070903).

- The MyLabFive represents an evolution of the ESAOTE Europe MyLab40 system with regard to the technical capabilities: most of the hardware architecture is the same, the software driving the device is the same, the optional trolley providing an insulation transformer for safe peripherals connection are comparable to the trolley of the ESAOTE Europe MyLab40.
- Clinical uses for which the MyLabFive is designed are identical to those cleared for the ESAOTE MyLab40 via K070903.
- The MyLabFive Laparoscopic application makes use of the same design criteria of the ESAOTE 7340 (MyLab30 Gold Cardiovascular) cleared via K081794.
- The MyLabFive, ESAOTE 7340 (MyLab30 Gold Cardiovascular) and the ESAOTE Europe MyLab40 are designed to meet the IEC60601-1 and IEC60601-2-37 safety requirements.
- The MyLabFive, ESAOTE 7340 (MyLab30 Gold Cardiovascular) and the ESAOTE Europe MyLab40 provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values
- The MyLabFive, ESAOTE 7340 (MyLab30 Gold Cardiovascular) and the ESAOTE Europe MyLab40 provide a similar measurements and analysis package, with equal accuracy and precision.
- The MyLabFive, ESAOTE 7340 (MyLab30 Gold Cardiovascular) and the ESAOTE Europe MyLab40 have digital storage capabilities, including Network connectivity.
- Both the MyLabFive and the ESAOTE 7340 (MyLab30 Gold Cardiovascular) (K081794) are designed to be powered by battery when no main power is available.
- The MyLabFive MView mode is available on other FDA cleared ultrasound systems, for instance the Esaote Europe MyLab40 cleared via K070903.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Esaote Europe, B.V.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JAN 30 2009

Re: K083882
Trade/Device Name: MyLabFive
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: January 14, 2009
Received: January 15, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the MyLabFive, as described in your premarket notification:

Transducer Model Number

PA230
PA122
LA332
LA523P
C5-2 R13
CA123
CA631
2 CW
5 CW

EC1123
TRT33
TEE022
TEE122
IOE323
LP323
1-5PA

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K083882

Device Name: MyLabFive

Esaote's MyLabFive is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Laparoscopic, Intraoperative Abdominal, and Other Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

[Signature]
(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K083882

Prescription Use ✓
(Per 21 CFR 801.109)

MyLabFive

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	N	N	N		N	N	N		N	5, 6, 7
Abdominal	N	N	N	N	N	N	N		N	5, 6
Intraoperative (Abdominal)	N	N	N		N	N	N		N	5, 6, 10
Intraoperative Neurological										
Pediatric	N	N	N	N	N	N	N		N	5, 6, 10
Small Organ [1]	N	N	N		N	N	N		N	4, 5, 6, 10
Neonatal Cephalic	N	N	N	N	N	N	N		N	5, 6
Adult Cephalic	N	N	N	N	N	N	N		N	6
Cardiac [2]	N	N	N	N	N	N	N	N	N	4, 6, 8, 9
Transesophageal (Cardiac)	N	N	N	N	N	N	N	N	N	4, 6, 8, 9
Transesophageal (Non Cardiac)										
Transrectal	N	N	N		N	N	N		N	5, 6, 10
Transvaginal	N	N	N		N	N	N		N	5, 6
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N	N	N	N	N		N	5, 6, 7, 9, 10
Laparoscopic	N	N	N		N	N	N		N	5, 6, 10
Musculo-skeletal Conventional (including Nerve Blocking)	N	N	N		N	N	N		N	4, 5, 6, 10
Musculo-skeletal Superficial (including Nerve Blocking)	N	N	N		N	N	N		N	4, 5, 6, 10
Other (Urological)	N	N	N		N	N	N		N	5, 6

[1]

Small Organs includes Breast, Thyroid and Testicles

[2]

Cardiac is Adult and Pediatric

[3]

Combined modes are: B + M + PW + CW + CPM + PD

[4]

CMM

[5]

MView

[6]

XView

[7]

QIMT

[8]

Stress

[9]

Strain

[10]

TP View

Prescription Use
(Per 21 CFR 801.109)

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5083882

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P	P	P	P	P		P	6
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P		P	6
Cardiac [2]	P	P	P	P	P	P	P	P	P	4, 6, 8, 9
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The PA230 probe was previously cleared via K070903

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View

Prescription Use ☒
 (Per 21 CFR 801.109)

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Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Petal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	6
Small Organ [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	6
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	P	P	4, 6, 8, 9
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	6, 9
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The PA122 probe was previously cleared via K070903

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View

Prescription Use ☒
 (Per 21 CFR 801.109)

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Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement (Imaging (TEI))	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6, 10
Small Organ [1]	P	P	P		P	P	P		P	4, 5, 6, 10
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 7, 9, 10
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 10
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 10
Other (Urological)										

The LA332 probe was previously cleared via K081794

- (1) Small Organs includes Breast, Thyroid and Testicles
 (2) Cardiac is Adult and Pediatric
 (3) Combined modes are: B + M + PW + CW + CFM + PD
 (4) CMM
 (5) MView
 (6) XView
 (7) QIMT
 (8) Stress
 (9) Strain
 (10) TP View

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Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6, 10
Small Organ [1]	P	P	P		P	P	P		P	4, 5, 6, 10
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 7, 9, 10
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 10
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 10
Other (Urological)										

The LA523P probe is to be cleared via this submission

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View


Prescription Use ☒
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Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	5, 6, 7
Abdominal	P	P	P		P	P	P		P	5, 6
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6
Small Organ [1]										
Neonatal Cephalic	P	P	P		P	P	P		P	5, 6
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 9
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The C5-2 probe was previously cleared via K081794

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View


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Prescription Use ☒
 (Per 21 CFR 801.109)

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6
Small Organ [1]	P	P	P		P	P	P		P	4, 5, 6
Neonatal Cephalic	P	P	P		P	P	P		P	5, 6
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	4, 5, 6
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 9
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6
Other (Urological)										

The CA123 probe was previously cleared via K070903

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CPM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View

Prescription Use
 (Per 21 CFR 801.109)

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Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	5, 6, 7
Abdominal	P	P	P		P	P	P		P	5, 6
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 9
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6
Other (Urological)	P	P	P		P	P	P		P	5, 6

The CA631 probe was previously cleared via K070903

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CPM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View

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Division of Reproductive, Abdominal and Radiological Devices

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Prescription Use ✓
 (Per 21 CFR 801.109)

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				P						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The 2CW probe was previously cleared via K070903

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac in Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View

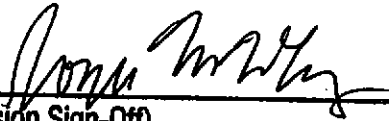
Prescription Use 
 (Per 21 CFR 801.109)


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 Division of Reproductive, Abdominal and
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Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The 5CW probe was previously cleared via K070903

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View


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Prescription Use ☒
 (Per 21 CFR 801.109)

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	5, 6, 7
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	5, 6
Transvaginal	P	P	P		P	P	P		P	5, 6
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	5, 6

The EC1123 probe was previously cleared via K081794

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View

[Signature]
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Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K083882

Prescription Use ☒
 (Per 21 CFR 801.109)

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	5, 6, 10
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	5, 6, 10

The TRT33 probe was previously cleared via K081794

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View

[Signature]
 (Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K083882

Prescription Use ☒
 (Per 21 CFR 801.109)

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	4, 6, 8, 9
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The TEE022 probe was previously cleared via K070903

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View

Prescription Use ☒
 (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and
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Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	4, 6, 8, 9
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The TEE122 probe was previously cleared via K070903

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] XView
 [7] QIMT
 [8] Stress
 [9] Strain
 [10] TP View

Prescription Use ☒
 (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083882

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	5, 6, 10
Intraoperative (Abdominal)	P	P	P		P	P	P		P	5, 6, 10
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6, 10
Small Organ [1]	P	P	P		P	P	P		P	4, 5, 6, 10
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 9, 10
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 10
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 10
Other (Urological)										

The IOE323 probe was previously cleared via K070903

- [1]
- [2]
- [3]
- [4]
- [5]
- [6]
- [7]
- [8]
- [9]
- [10]

Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Combined modes are: B + M + PW + CW + CFM + PD
 CMM
 MView
 XView
 QIMT
 Stress
 Strain
 TP View


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 510(k) Number K083882


Prescription Use _____
 (Per 21 CFR 801.109)

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	5, 6, 10
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic	P	P	P		P	P	P		P	5, 6, 10
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The LP323 probe was previously cleared via K051837 & K081794

- (1) Small Organs includes Breast, Thyroid and Testicles
 (2) Cardiac is Adult and Pediatric
 (3) Combined modes are: B + M + PW + CW + CFM + PD
 (4) CMM
 (5) MView
 (6) XView
 (7) QIMT
 (8) Stress
 (9) Strain
 (10) TP View


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 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K083882

Prescription Use 
 (Per 21 CFR 801.109)

1-5PA

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	N	N	N	N	N	N	N		N	6
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic	N	N	N	N	N	N	N		N	6
Cardiac [2]	N	N	N	N	N	N	N	N	N	4, 6, 8, 9
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The 1-5PA probe is to be cleared via this submission

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [5] MView
- [6] XView
- [7] QIMT
- [8] Stress
- [9] Strain
- [10] TP View

Prescription Use ☒
(Per 21 CFR 801.109)

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